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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/981,998	05/11/1998	STEFAN M. PULST	232.00010120	8733

7590 06/03/2002  
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EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 06/03/2002

36

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

08/981,998

Applicant(s)

PULST, STEFAN M.

Examiner

Jeanine A Goldberg

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,5,7,59,61 and 71-84 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3,5,7,59,61,71-73,75-77 and 80-84 is/are allowed.
- 6) ☒ Claim(s) 74,78 and 79 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 33, 35.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. This action is in response to the papers filed March 5, 2002.
2. Currently, claims 1-3, 5, 7, 59, 61, 76-84 are pending. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow. This action is FINAL.
3. Any objections and rejections not reiterated below are hereby withdrawn.
4. This action contains new grounds of rejection necessitated by amendment.

### *Priority*

5. The examiner notes that the response asserts that certain parts of certain sequences are deemed earlier priority dates. For the purpose of clarity, the sequences which are found in the pending claims are provided the following priority dates.
6. It is noted that SEQ ID NO: 19 has been added from the parent application. SEQ ID NO: 19 appears to contain only about 400 amino acids from the 1135 amino acids of the full length mouse SCA2 polypeptide. Thus, SEQ ID NO: 19 appear to be a partial polypeptide for the full length mouse SCA2 polypeptide. While SEQ ID NO: 19 appears to have priority to October 8, 1996, a claim drawn to a nucleic acid encoding a full length SCA2 polypeptide is enabled only as of May 8, 1997 when the full length mouse polypeptide was described.

SEQ ID NO: 1 nucleotides 1-516	October 8, 1996
SEQ ID NO: 2 nucleotides 163-4098 (coding portion)	October 8, 1996
SEQ ID NO: 2 nucleotides 163-657 (5' coding portion)	October 8, 1996
SEQ ID NO: 2 nucleotides 724-4098 (3' coding portion)	October 8, 1996
SEQ ID NO: 4 nucleotides 50-3454 (coding portion)	May 8, 1997
SEQ ID NO: 4	May 8, 1997
SEQ ID NO: 5	May 8, 1997
SEQ ID NO: 6	May 8, 1996
SEQ ID NO: 7	May 8, 1996
SEQ ID NO: 19 (newly added from parent application)	October 8, 1996

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Newly added Claims 74, 78-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A2) Claim 74 is indefinite because it is unclear whether the claim is limited to a nucleic acid comprising SEQ ID NO: 19 or whether the claim encompasses a nucleic acid comprising a portion of SEQ ID NO: 19. A nucleic acid comprising a portion of

SEQ ID NO: 19 are set forth in SEQ ID NO: 19. In the event that the claim was intended to encompass a fragment of SEQ ID NO: 19 embedded within larger sequences, the claim would encompass all nucleic acids since all nucleic acids encompass either an "A, T, C or G". Therefore, it is presumed that the claim is intended to be directed to a nucleic acid comprising SEQ ID NO: 19 which is essentially identical to Claim 75 (see rejection below).

B2) Claims 78-79 are indefinite over the recitation "at least about". The phrase "at least about" because the metes and bounds of the invention are not clear. As the CAFC noted, and affirmed, regarding the district court determination of this phrase in *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.* (CA FC) 18 USPQ2d 1016 at page 1031 "the court held the "at least about" claims to be invalid for indefiniteness." Here too, the situation is that the claim is indefinite with regard to the values encompassed.

### ***Double Patenting***

8. Claim 74 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 75. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The only difference between newly amended Claim 74 and Claim 75 is an "a" and "the" following comprising. In the event that "a" and "the" are identical, the claims are identical.

***Allowable Subject Matter***

9. Claims 1-3, 7, while not containing a specific SEQ ID NO have provided adequate description of a nucleic acid which is from a specific chromosomal region, which encodes a polypeptides of a certain weight, which contains at least 35 CAG repeats and causes symptoms of spinocerebellar ataxia. Therefore, both structure and function have been provided.
10. Claim 5, 83 contains both hybridization language and functional language such that the claim encompasses nucleic acids which hybridize to the regions of SEQ ID NO: 1 and 2, but also encodes SEQ ID NO: 3.
11. Claims 59, 61, 73, 75, 82, 84 are allowable over the art. The prior art does not teach the SCA2 nucleic acid from the mouse which are SEQ ID NO: 4, 5, 19 (limitations of Claims 59 and 61).
12. Claims 71,72, 76-77, 80-81 directed to SCA2 nucleic acids of nucleotides 163-4098 of SEQ ID NO: 2, encoding the amino acid sequence of SEQ ID NO: 3, SEQ ID NO: 6-7 are allowable.

***Conclusion***

13. Claims 1-3, 5, 7, 59, 61, 71-73, 75-77, 80-84 are allowable.
14. Claims 74, 78-79 are rejected.
15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

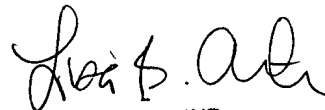
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of formal matters can be directed to the patent analyst, Pauline Farrier, whose telephone number is (703) 305-3550.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Goldberg  
May 22, 2002



LISA B. ARTHUR  
PRIMARY EXAMINER  
GROUP 1800 1600